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INTRAUTERINE DEVICES: THEIR ROLE IN FAMILY PLANNING CARE

World Health Organization
Geneva

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INTRAUTERINE DEVICES

Their role in family planning care

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PREFACE

This publication has been compiled for the information of those involved in the planning and management of family planning services.

The aim of this book is:

- to provide technical guidance for health administrators and programme planners on how to incorporate the provision of IUDs into a health care system, and
- to provide information on the recent clinical knowledge on IUDs to different categories of health workers as well as to health administrators.

The views summarized in this publication are those most widely accepted at present, and they are based on a critical review of a large number of clinical studies and field trials. The most important source of this information has been the WHO Special Programme of Research, Development and Research Training in Human Reproduction (especially its Task Force on IUDs) and the Population Council's Cooperative Statistical Programme.

This document does not provide firm guidelines, but details various points that may be important when planning services or making managerial decisions.

This book is the fifth in a series of technical documents on family planning technology that have been published by WHO since 1976. The other four concerned female sterilization,[a] induced abortion,[b] oral contraceptives,[c] and injectable contraceptives.[d]

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[a] Female sterilization: guidelines for the development of services. Geneva, World Health Organization, 1976 (WHO Offset Publication No. 26)

[b] Induced abortion: guidelines for the provision of care and services. Geneva, World Health Organization, 1979 (WHO Offset Publication No. 49)

[c] Oral contraceptives: technical and safety aspects. Geneva, World Health Organization, 1982 (WHO Offset Publication No. 64)

[d] Injectable hormonal contraceptives: technical and safety aspects. Geneva, World Health Organization, 1982 (WHO Offset Publication No. 65)

1. INTRODUCTION

The intrauterine device (IUD) has become one of the most widely used and safest methods of contraception available, during the last two decades. At present, it is estimated that IUDs are used by 65 million women, 50 million of whom are in the People's Republic of China.

IUDs were developed at the beginning of the twentieth century but were not widely used until the development, in the sixties, of the new plastic, pliable devices, such as the Lippes Loop; it was then that the IUD became popular as a method of contraception.

Once inserted, the IUD usually stays in place as long as required without any further action being necessary, which is advantageous for both the women concerned and the family planning services. The contraceptive effect is easily reversible by removal of the IUD, unlike sterilization. However, as with most contraceptive methods, the IUD can produce side-effects, such as heavy menstruation and/or pain.

The choice of contraceptive method depends on the attitude of both the general population and the medical profession; local public reaction to rumours or mass-media reports of potential complications is often exaggerated and health workers must, therefore, be responsible for evaluating all the information on the suitability of the contraceptive methods that are available.

Recognition and discussion of the limitations of the IUD should increase rather than diminish its important role in family planning. Critical evaluation of IUDs for more than two decades has shown them to be a generally safe, effective, and practical form of fertility regulation, and they have been used in national programmes in many countries. The use of IUDs in a health service programme does, however, require special staff training and the provision of some minimum facilities and equipment which may limit their availability in some cases.

This document does not aim to make specific recommendations for family planning services, nor does it promote or condemn any of the fertility regulating methods. It is intended, firstly, to provide a discussion of the technical issues related to the provision and use of IUDs and, secondly, to point out how scientific data on IUDs can be used in the planning and management of health services. Although it may contain useful material for the training of doctors and nurses, this is not its main purpose. For such a training manual the reader is referred to the WHO publication by R. H. Gray (see "Selected Bibliography").

2. THE INTRAUTERINE DEVICE

In principle, an IUD can be any foreign object inserted into the uterine cavity and left there in order to prevent a pregnancy. The first devices were simple coils of silk or metal threads. Modern devices are mostly made of soft, pliable plastic, in various shapes, and are designed to be temporarily fitted into an introducer which may be inserted through the cervix into the uterine cavity; once in place, the IUD resumes its original shape.

2.1 Types of IUD

There are two basic types of IUD: non-medicated and medicated. Both are usually made of polyethylene or other polymers; in addition, the medicated types incorporate a system that releases a chemical substance into the uterine cavity at a constant rate, for instance, copper or progestational steroids. These medicated IUDs were developed to reduce the incidence of side-effects (particularly bleeding) and to increase the contraceptive effectiveness. However, they are more expensive and must be changed after a certain time to maintain their effectiveness. The drug regulatory authorities have recommended that the copper devices be changed every two years, but clinical evidence shows that they can be effective for at least three years.

There is a great variety in the design of the devices. The characteristics, advantages, disadvantages, etc., of the most commonly used devices and insertion systems are described in detail in Annex 1.

2.2 Mechanisms of action

The specific mechanism of the antifertility effect of IUDs has not yet been conclusively established. Much of the research on animals is now known to be inapplicable to women in whom it is clear that IUDs do not suppress ovulation, interfere with the corpus luteum, accelerate the transport of the fertilized egg, or completely inhibit sperm transport and fertilization. It has been suggested that they stimulate phagocytosis, release prostaglandins locally, or interfere with the enzyme systems involved in implantation. At present, the most widely accepted view is that they cause a foreign-body reaction in the endometrium associated with leukocyte infiltration which leads

to rejection of the fertilized ovum and its failure to implant.

Copper, which adds to the antifertility effect of the medicated devices, seems to enhance the cellular response in the endometrium to the foreign body, but any other action it may have is not known.

3. THE ROLE OF THE IUD IN FAMILY PLANNING

3.1 Advantages of the IUD

Once inserted, the IUD is effective for several years; this is a major advantage for the woman involved and for the services responsible for the provision of family planning care. No further action is needed to prevent a pregnancy, either daily as with oral contraceptives, or in connexion with coitus as with barrier methods. The IUD is particularly suitable for women who want to avoid pregnancy but for various reasons cannot follow the precise schedule required with contraceptives, or cannot use them for medical reasons. Unlike surgical sterilization the antifertility effect of the IUD is readily reversible by its removal.

The IUD method is virtually free of systemic effects, but, as with other contraceptive methods, the IUD can produce side-effects and complications. Therefore, use of the IUD requires certain health care facilities and trained personnel to take care of these complications, should they arise.

3.2 Effectiveness and continuation rates

There are three contraceptive methods that offer more reliable protection against unwanted pregnancies than the older barrier techniques; these are intrauterine devices, oral contraceptives, and injectable contraceptives. The theoretical (or method-related) effectiveness of IUDs is less than that of the two other methods. However, if factors such as user-related failures and continuation rates are taken into account, the effectiveness of IUDs is comparable with that of the other methods.

The pregnancies reported in IUD users often include those occurring after unnoticed expulsions as well as with the device in place. The IUD offers slightly less protection against unwanted pregnancies than regular injections of depot-medroxyprogesterone acetate (DMPA) or oral contraceptives taken conscientiously, but for a variety of reasons (personal, medical, or cultural), the IUD has a higher continuation rate than the other two methods in certain populations. The introduction of the smaller medicated devices has also allowed the effective use of IUDs in women who have never been pregnant or have

a small uterus. These devices are more effective than the Lippes Loop, are easier to insert, and are associated with less pain and bleeding.

Several reports have emphasized the complexity of the factors governing the continued use of IUDs. These factors include the type of patient, especially in relation to age and gravidity, the motivation behind the choice of method, the physician's acceptance of side-effects, and clinical practice in follow-up care. While oral contraceptives are theoretically more effective, they have been shown to have drop-out rates after one or two years that are at least as high as for the IUD, while the overall effectiveness in family planning programmes are similar for the two methods. The drop-out rates for injectable contraceptives are often higher than those for IUDs, possibly because of disturbances in menstrual patterns which, for cultural or religious reasons, are often not acceptable.

4. PROVISION OF IUD SERVICES

Intrauterine devices should preferably be available at any family planning clinic, or other health facility offering integrated family planning services. However, this method requires more trained personnel, facilities, and equipment than does, for instance, the provision of condoms or oral contraception. It is therefore normally offered in clinics, which can be either permanent or well equipped mobile units. In some countries the provision of IUDs has been considerably extended using specially trained workers carrying out insertions in the home in rural areas.

Wherever the IUD insertion is carried out, it is necessary to provide optimal back-up facilities to deal with immediate complications such as syncope, cramps, and bleeding. A referral system must be established for cases with an immediate complication, such as perforation and excessive bleeding, and cases requiring follow-up investigations and treatment. The referral centre should be staffed with a qualified gynaecologist or surgeon and adequately equipped with the facilities necessary to carry out abdominal surgery and, possibly, laparoscopy.

This chapter discusses some aspects related to the provision of services that are more or less specific for IUDs. A more detailed discussion of aspects of family planning provision within primary health care programmes (dealing with a variety of fertility regulating methods) is in preparation by WHO.

4.1 Who should perform the IUD insertion?

In most countries, IUD insertion is mainly (often exclusively) carried out by doctors. This is often in order to comply with laws or regulations for health service personnel. However, a large number of successful programmes in many developing and developed countries have shown that a properly trained nurse-midwife, or even an auxiliary midwife, can provide as good an IUD service as the average doctor.

In Sweden, experience has shown that a nurse-midwife, after suitable training, either basic training or in-service training, provides an IUD service as good as that

of the trained gynaecologist, in terms of performance rates. The continued use of the IUD by women supervised by midwives is even better than by those supervised by doctors.

WHO studies in Turkey and the Philippines comparing the provision of IUD service by trained assistant nurse midwives (ANMs) and by physicians, have clearly shown that the ANMs can provide standards of clinical care for IUD users comparable with those provided by a physician. In both studies, similar results were obtained regarding discontinuation following expulsion, medical removal, and pregnancy. Moreover, the physicians and the ANMs achieved a comparable level of diagnostic accuracy in detecting contraindications to, and complications of, IUD use.

Similar to the experience in Sweden, there is some evidence from the WHO studies that ANMs may provide a more effective service because of their greater acceptability and accessibility to the user.

In places where different categories of health worker have been used in IUD distribution programmes, their professional background appears to be less important than a well designed and well conducted practical training programme.

In any family planning system, the training given to the personnel who will perform IUD insertions must ensure that the participants:

- understand the concepts and rationale of family planning,
- are capable of describing the different contraceptive methods available and their potential risks and benefits,
- can identify the cases with contraindications to IUD insertion and abnormal or doubtful cases that require referral to a physician,
- have acquired sufficient practical skill to insert IUDs without supervision,
- can recognize complications and make the necessary referrals,
- know how to instruct women on possible side-effects and emphasize the need to return for follow-up examination,

- know how to maintain basic records for the management of patients and programme evaluation.

The length of this kind of training will be determined by the level of basic knowledge and experience of the trainees and by the capacity of the clinical facilities where they are to be taught.

4.2 Role of community health workers

There are few circumstances in which it is necessary to consider training traditional birth attendants or other types of community worker to perform IUD insertions. However, they can, if properly trained and supported, perform other very important functions in relation to the use of IUDs. In particular, this includes identifying couples in need of family planning advice, informing them about methods and the availability of services, and assisting the clinic in follow-up investigations, and the detection of complications or other problems.

In order to carry out these activities, the community workers need additional information. The possibilities of including such information and education in existing or newly-planned training programmes for these workers should be explored.

4.3 Counselling

Some women have already decided before they attend the clinic which form of fertility regulation they wish to use, even though it may be unsuitable; others leave the decision entirely to the clinic. In both cases, the counsellor must explain to the patient the advantages and disadvantages, without causing any unnecessary alarm. Myths have grown up about some family planning methods, and a good counsellor should try to encourage the patient to discuss all her fears openly. The possible side-effects should be explained thoroughly as this will increase the patient's confidence in the method and in the counsellor. In addition, she may then be more willing to continue with the method until the side-effects disappear spontaneously.

Counselling should ideally involve both the woman and her partner, and the couple should feel they are being offered the method that is best suited for them

- not just the one that is currently being promoted by the clinic. All fertility regulating methods are more effective when the counselling and follow-up are good. Audiovisual aids and models may be useful to explain the techniques and answer questions on particular methods.

Successful family planning programmes usually emphasize the importance of personal contact and of assuring the user that advice on any problems is readily available.

Before leaving the clinic, the woman should know:

- the date and place of her follow-up appointment and how to make an earlier appointment if problems arise;
- that minor side-effects like spotting, heavier menses, and some cramps are common, but tend to decrease after three months;
- how to feel for the threads and what to do if she is unable to feel them or suspects she is pregnant.

Although counselling in busy clinics may be carried out by a special nurse or social worker, the person carrying out the insertion should provide further reassurance, since this will help to improve the use-effectiveness and continuation rates.

5. REQUIREMENTS FOR AN IUD SERVICE

To provide safe and acceptable services for IUD insertion, whether integrated into general health services, in special family planning clinics, or in special mobile clinics, there are certain basic requirements.

5.1 Clinical requirements

5.1.1 Facilities

The minimum facilities that should be available are:

- a reception and record-keeping area;
- a private area for consultation and counselling;
- a curtained or separate area for pelvic examinations, insertions, and removals;
- facilities for washing and sterilizing equipment;
- toilets.

These can usually be accommodated within existing clinic facilities. Where possible a recovery area with a couch, should also be provided.

5.1.2 Equipment

A standard kit for IUD insertions is available[a] and has been in use for some time. It consists of:

- metal sterilization tray with cover,
- bivalve specula - small, medium, and large,
- tenaculum,
- sponge forceps,
- long straight artery forceps,
- uterine sound,
- torch with batteries,
- scissors,
- benzalkonium chloride solution 1:75 (13.3 g/litre) or aqueous iodine solution 1:2500 (0.4 g/litre)

The number of sets of instruments required will depend on the clinic workload and the facilities available for sterilization of the equipment. A couch

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[a] Through UNICEF or the Agency for International Development (USAID).

or gynaecological examination table must be available. Although a torch provides adequate lighting, a light source on a floor stand is more convenient and will make it possible to insert the IUD without an assistant.

Sterilization of the instruments is essential. Metal instruments may be sterilized by boiling, but IUDs and the introducers are deformed by heating and must be sterilized by immersion in antiseptic solutions which should be changed daily. The IUDs and the inserters should be immersed in the benzalkonium chloride solution for 24 hours or in the aqueous iodine solution for 10 minutes. The IUD should not be left in the benzalkonium chloride solution for more than 24 hours as the plastic may become brittle and lose its elasticity; if this happens it will not return to its original shape after insertion.

The most commonly used sterilizing solutions for IUDs and inserters are benzalkonium chloride and iodine. Benzalkonium chloride solution is available commercially at a dilution of 1:750 (1.33 g/litre). The aqueous iodine solution (1:2500 - 0.4 g/litre) should be freshly prepared daily as follows: 25 ml of 2% tincture of iodine in 1 litre of water or 7 ml of 7% tincture of iodine in 1 litre of water. In clinics where only chemical sterilization methods are available, it may be difficult to cope with several insertions at any one time.

5.1.3 Supplies

An area where simple laboratory tests can be performed is not essential, but will improve the services offered. If laboratory tests are carried out, the necessary chemicals must be readily available (see Annex 2).

The IUDs are supplied individually packed or in bulk packs with several separate introducers; the price difference between these packs is considerable. The shelf-life of both pre-sterilized and other IUDs is long, and in services with limited equipment and sterilization facilities, which carry out few insertions, it is often preferable to use the pre-packed IUDs.

A regular supply of the sterilization solutions for instruments and vaginal preparation, antiseptics and cotton-wool should be available, and storage facilities for these will be required.

5.1.4 Staff requirements and training

To provide a satisfactory IUD service, each clinic must have enough adequately trained professional staff to provide continuity of patient care and access to a physician or a medical clinic if necessary. The trained staff should be preferably female, since a pelvic examination is necessary at every visit and teaching a woman to squat and feel for the threads may be more acceptable if the teacher is a woman; this is essential in certain countries for religious and moral reasons.

Additional staff for reception, administration, cleaning, and maintenance duties may be provided, depending on the local conditions and the budget available.

If the IUD insertions are not carried out by doctors, the personnel involved must undergo practical training and be supplied with manuals and other relevant information. This may also apply to medical practitioners.

This staff training should cover both the theoretical and practical aspects of IUD insertion, possible complications, and clinical regimes, including aseptic techniques, sterilization procedures, equipment maintenance and supply, record-keeping and use, and the practical implications of any laboratory procedures to be provided. The training may include lectures, the use of audiovisual aids, and demonstrations. However, experience in IUD insertion and in pelvic examination can only be acquired by apprenticeship in the service. The amount of training and supervision required will depend on the local conditions. The staff must be able to perform competently all the tasks required and recognize when it is necessary to ask for a medical opinion. Physicians should be readily available for supervision and evaluation, for consultation about case selection, and for the treatment of side-effects and complications.

The WHO publication Manual for the provision of intrauterine devices (see "Selected Bibliography") is a useful reference for the training programme and also subsequently as a field manual. It has been field-tested for this purpose in Turkey and the Philippines. It must be stressed, however, that all training programmes should be carefully adapted to the local conditions and problems.

5.1.5 Laboratory tests

If local conditions are favourable, simple laboratory tests should be performed.

Tests that may be performed in the centre, if applicable	Equipment required (see also Annex 2)
Haemoglobin estimation	Haemoglobinometer; skin stylette
Erythrocyte sedimentation rate	Set of Westergren tubes and stand; cannulas for venepuncture
Pregnancy test	Pregnancy test kit
Microscopy of vaginal discharge	Microscope (x40); Gram staining solutions; and glass slides
Samples to be sent to the laboratory, if applicable	
Papanicolaou smear	Glass slides; wooden spatula; transport container for slides; 95% alcohol solution

The examination of Papanicolaou smears requires adequate laboratory facilities and good follow-up services.

In deciding which tests should be carried out, and whether they should be done at the clinic or in a laboratory, both financial and labour costs must be balanced against the relevance of the test for the women to be fitted with an IUD. The estimation of haemoglobin, for instance, is directly relevant to a common IUD complication - bleeding. In contrast, women fitted with an IUD do not have an increased risk of cancer of the cervix (see section 7), and consequently do not specifically need to be screened using Papanicolaou smears.

5.1.6 Records and filing system

A records system is needed that not only allows the simple recording of IUD acceptors, but also assists in the follow-up of cases, and the monitoring and evaluation of the programme. Methods of record-keeping and their use should be included in the basic and in-service training of both health workers and supervisors. The system should be designed to assist the worker in case-monitoring. It could, for instance, contain a check-list for risk factors and contraindications (see Annex 3).

5.2 Clinical and technical procedures

The items included in this section have been discussed in detail in the WHO publication Manual for the provision of intrauterine devices (see "Selected Bibliography"); some aspects will be dealt with here in more detail.

5.2.1 History and physical examination

A case history must be obtained from the woman with special reference to any pregnancies, the menstrual cycle, and past or present genital tract infections. A careful abdominopelvic examination must follow: the size, shape, and position of the uterus must be defined and conditions such as gynaecological infections excluded. It is useful to have a check-list for both the history and the physical examination so that no contraindications are overlooked; this is especially important where personnel other than doctors provide the service (see Annex 3). Laboratory tests are not essential before the insertion of an IUD, but the service to the patient is improved if some of the tests listed (section 5.1.5) are available. A clinical assessment for the possible presence of severe anaemia should always be carried out if laboratory tests for haemoglobin levels are not available.

5.2.2 Choice of method

A woman's choice of contraceptive method from the variety available, should be an informed one. Medical considerations may suggest that a particular method is more suitable, but for the method to be successful the

woman must feel that she makes the final decision and that the method chosen is the best for her.

Absolute contraindications for the insertion of an IUD

- carcinoma of the corpus uteri or cervix, or vaginal bleeding of undiagnosed etiology
- suspected pregnancy
- active pelvic inflammatory disease
- previous ectopic pregnancy

Relative contraindications

- anaemia[a]
- menorrhagia
- a history of pelvic inflammatory disease since last pregnancy
- purulent cervical discharge
- congenital uterine malformation or cavity distortion (fibromas, etc.).

The age of the woman, whether very young or near the menopause, is not a contraindication for IUD use, but there are special problems for these age-groups that must be taken into account (see sections 6.3.1 and 6.3.2).

5.2.3 Timing of insertion

It is usually recommended that the IUD should be inserted during menstruation or soon after, when it is easier and a pregnancy can be ruled out. However, it is more practical to carry out the insertion when the woman presents herself, rather than asking her to come back at the time of the next menstruation. Before doing so, it should be ascertained that conception is unlikely to have occurred, by obtaining an accurate history of menstruation dates and the date of the last intercourse, etc. If pregnancy cannot be definitely ruled out, an alternative temporary method should be prescribed and the woman encouraged to return for the

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[a] The actual blood haemoglobin concentration (g/litre) has to be locally defined.

insertion of an IUD immediately after her next period. IUDs can also be inserted postpartum or after spontaneous or legally induced abortion (see sections 6.3.3 and 6.3.4).

5.2.4 Technique of insertion

Each device and insertion system has its own special features and in each case the manufacturer's instructions should be studied carefully. There are, however, some general principles that apply to most devices and insertion systems:

(1) Unless the device and introducer are already sterilized in a sealed package, both must be sterilized before insertion by soaking in an antiseptic solution.

(2) A pelvic examination must be carried out to establish the size, position, and flexion of the uterus, and a speculum inserted into the vagina to expose the cervix so that any infection or other pathological condition can be excluded.

(3) The vagina and cervix should be cleansed with a suitable antiseptic agent (e.g., polyvidone-iodine solution - concentration 7.5 - 10.0 g/litre).

(4) The cervix should be grasped with a tenaculum, gentle traction applied downwards to reduce the uterine flexion, and a probe passed through the cervix to measure the length and confirm the direction of the uterine cavity. If the length of the uterine cavity and cervix is less than 6.0 cm, an IUD is unlikely to be the best choice of method.

(5) The device should be loaded into the inserter, taking full sterile precautions, and the movable flange, if fitted, adjusted to the length of the uterus as indicated by the probe measurement.

(6) The loaded device should be inserted through the cervix and released in the transverse plane of the uterus using the technique described in the manufacturer's instructions.

(7) The inserter is then withdrawn and the threads (if present) cut at a distance of approximately 2.5 cm from the external os. The threads then tend to remain attached to the vaginal wall by the cervical secretion. Threads that are too short can sometimes be felt by the partner during intercourse.

5.2.5 Change of IUD

Non-medicated devices may be left in place as long as required if they do not produce any major problems. Tubal ligation or vasectomy, as an alternative to prolonged IUD use should be discussed with couples who have completed their families.

The effective life span of bioactive or medicated devices, as stated by the manufacturers, determines the duration of use before they need to be changed. This is an inherent disadvantage of these devices when they are used in large national family planning programmes, especially in developing countries. When devices are removed because of side-effects such as bleeding or pain, it has been recommended previously that there should be a time-lapse of at least one menstrual cycle before another IUD is inserted. However, this is not necessary if there is no recognized contraindication to the reinsertion of an IUD.

5.2.6 Removal of IUD

An IUD can usually be removed easily, with only slight discomfort to the patient. The cervix is exposed with a speculum, the threads are simply grasped with forceps and gentle downward traction is applied.

Any difficulty or pain during removal may be due to partial or complete translocation or embedding of the IUD. In such cases, or if the threads of an IUD have become displaced upwards or broken, removal of the device may be difficult, and it is usually advisable to refer the woman to a well equipped clinic.

Indications for removal

Indications for removal may be medical or personal.

Medical:

- pregnancy (only if the threads are visible and removal is easy),
- excessive bleeding,
- unacceptable lower abdominal pain,
- signs of pelvic inflammatory disease,
- known or suspected uterine or cervical neoplasia.

Personal:

- desire for pregnancy,
- change of method,
- no further need for protection against pregnancy.

5.2.7 Follow-up procedures

The objectives of the follow-up are:

- to provide reassurance and to assist the patient if she wants to change to another method,
- to assess the patient's general health, including anaemia, and to treat any problems that arise,
- to diagnose unnoticed expulsion of the IUD,
- to detect translocation or displacement and to reinsert an IUD, if necessary,
- to replace medicated devices at specified time intervals.

The first follow-up examination is usually carried out within three months of the insertion. Subsequent visits to the clinic can be made at six-month to one-year intervals, depending on the facilities and resources of the clinic and the convenience of the patient. At each follow-up visit a history should be taken with special reference to menstrual problems, pain, possible expulsion, or removal. A speculum and bimanual examination should preferably be carried out to see whether the threads are visible and to exclude pelvic inflammation or vaginitis.

If the woman cannot, or is unwilling to come to the clinic where the insertion was performed, supportive visits and further examination could be carried out by trained community health workers, if available.

6. CLINICAL MANAGEMENT

6.1 Method-related problems

The most frequent reasons for discontinuation are bleeding, pain, and expulsion of the device. Table 1 shows the discontinuation rates, in the first year of use for different reasons and for various types of IUD. These figures were obtained from several sources.

TABLE 1. EVENTS OCCURRING IN FIRST YEAR OF IUD USE (PERCENTAGE OF USERS AFFECTED)

Device	Pregnancy	Expulsion	Removal for bleeding or pain
Lippes Loop D	2.0-2.5	7.0-10.0	7.5-12.0
Copper-7	1.5-3.0	5.0-11.0	10.2-11.5
TCu-200	2.1-3.1	7.1- 8.1	9.0-11.5
TCu-220C	0.8-0.9	7.0- 8.0	11.5-13.1

6.1.1 Bleeding

Bleeding problems account for 10-20% of all IUD removals. This bleeding may occur as one or a combination of the following: increased menstrual flow, an increase in the duration of the menstruation, or inter-menstrual spotting.

IUD removal because of bleeding is often influenced by variables, such as cultural factors, the attitudes of the clinic and physician, women's acceptance of inconvenience, and the degree of motivation.

The total blood loss during each normal menstrual period is about 35 ml. WHO studies of menstrual blood loss (MBL), during two years after insertion in the users of various types of IUD, demonstrate a nearly uniform increase in MBL ranging from 20 to 120%, the greatest blood loss being in response to the larger non-medicated devices. Menstrual blood loss is consistently lower when progesterone releasing devices are used (Progestasert-TM) and following insertion of experimental devices releasing levonorgestrel.

Thus, objective studies have shown an increase in MBL with both inert and copper devices. A small number of women in the studies mentioned developed anaemia, with a significant decrease in the Hb level, but most had no decrease in Hb. On the other hand, serum ferritin levels, which reflect more accurately the body's iron stores, did fall progressively in women using large non-medicated devices. Women fitted with a Progestasert device showed a significant increase in serum ferritin levels indicating replenishment of the iron stores following the decreased menstrual blood loss.

It should also be mentioned that women who have heavier than normal menstrual blood loss before IUD insertion experience a smaller increase in bleeding after IUD insertion. This suggests that heavy menstrual periods should not automatically be regarded as a contra-indication for IUD use.

The removal of an IUD because of increased menstrual blood loss, a changed menstrual pattern, the risk of anaemia, or inconvenience for the woman, must be balanced against the availability of other contraceptive methods and the risk of an unwanted pregnancy.

In addition to the increase in menstrual blood loss, the duration of menstrual bleeding is often prolonged in women fitted with an IUD. Usually this prolongation involves a few days of pre- or post-menstrual spotting. This change in menstrual pattern is not a health risk for the woman, but it could have social and cultural implications. To increase the acceptance of the method, the IUD acceptors must be informed beforehand about these possible menstrual changes.

The treatment of any excessive blood loss continues to pose problems. WHO studies indicate that a decrease in IUD-induced heavy menstrual blood loss occurs following the use of any non-steroidal anti-inflammatory drug that is administered during the first days of menstruation. Anti-fibrinolytic drugs have also been effective. Reassurance and iron supplements should be provided but the device must be removed if the bleeding is very heavy or inconvenient to the patient or if she develops anaemia despite the iron supplement. A change

of device from the Lippes Loop to one of the smaller copper devices may help. In most women, removal of the device is rapidly followed by a return to the normal menstrual pattern. If an abnormal pattern persists, a full gynaecological investigation is required to exclude any possible associated pathological condition.

6.1.2 Pain

Slight pain is usually felt during the insertion of an IUD and may be followed over the next 10-15 minutes by cramping pains, which soon disappear. If, during insertion the pain is particularly severe, it is possible that the device has been placed in an incorrect position in the uterine cavity. Severe pain can also indicate a perforation of the uterine wall. Slight pain during insertion can usually be controlled by analgesics, such as aspirin. If severe pain persists, the device should be removed and the insertion of a smaller device considered.

Lower abdominal pain seems to depend on the size of the IUD in relation to the uterine cavity. Partial or complete expulsion is often accompanied by severe cramps and pain. In most reports, removal for bleeding and pain are classified together, but about 15-40% of removals appear to be for pain only and the others for bleeding and pain together. More serious complications such as pelvic inflammatory disease and ectopic pregnancy must be excluded before the IUD is considered to be responsible.

Increased menstrual pain (dysmenorrhoea) may accompany IUD use. This side-effect is more common among women who have never been pregnant. The progesterone-releasing device has been reported to diminish dysmenorrhoea in IUD users in some studies, but not in others.

6.1.3 Expulsion of the IUD

Expulsion of the IUD may be complete or incomplete. If incomplete, the stem of the IUD can be felt projecting through the cervical os and the contraceptive effectiveness is reduced. Expulsion is most common in the weeks immediately following insertion, and during menstruation. The expulsion rate depends on several factors such as the age and parity of the user (more common in young nulligravida), and the skill, and timing of the

insertion. Expulsion rates of up to 30% have been reported for postpartum insertions. If it is realized that expulsion has occurred, reinsertion is successful in two-thirds of the cases, but up to 20% of women may not notice that the device has been expelled. Larger devices and those with serrated edges that tend to become embedded in the uterine wall are more resistant to expulsion. In general, expulsion in itself is not a serious problem, but the user may become pregnant if it goes unnoticed.

6.1.4 Missing threads

If the IUD threads are not visible by speculum examination, there are a number of possible explanations: the device has been expelled, the threads were cut too short, or are coiled in the cervical canal, or are detached, the device has rotated, the uterus has enlarged pulling the threads upwards, or a perforation of the uterus has occurred.

A vaginal examination should be carried out to detect any uterine enlargement, and pregnancy should be excluded, if possible using a pregnancy test. For the personnel in a family planning clinic, without a specialist obstetrician, there are two possible options: either (a) to refer the woman to a better equipped clinic for exploration of the location (or expulsion) of the IUD, or if this is difficult or unacceptable (b) to insert a second IUD.

The most likely reason for the absence of the threads is that the expulsion of the IUD has gone unnnoticed. Even if the first IUD is still in place there are usually no additional problems when a second device is inserted. The possibility of a perforation of the uterus should be explored by looking for the characteristic signs (tender uterus, abdominal bleeding and/or infection).

6.1.5 Other problems

Vaginal discharge. An increased flow of odourless vaginal discharge is common, especially during the first few months following the insertion. If the discharge is not accompanied by other symptoms or signs of an infection, there is no need for any treatment other than reassurance.

Threads felt by partner. The rigidity of the transcervical thread varies greatly. Stiff threads, particularly if cut too short, tend to project from the cervical os and may cause penile trauma during intercourse. The threads should be cut to a length of about 2.5 cm; then they will tend to remain loosely attached to the vaginal wall by the cervical secretions.

6.2 Complications

6.2.1 Pregnancy with the IUD in situ

About 50% of intrauterine pregnancies occurring with the device in situ end in a spontaneous abortion. Removal of the IUD in early pregnancy has been found to reduce this abortion rate by half. In women who continue the pregnancy with the device in situ, a four-fold increase in the occurrence of premature births compared with other women, has been reported.

Reports have been published showing that there is an increased risk of intrauterine infection and septic abortion in pregnancies occurring with the device in situ, and the mortality rate due to this particular complication is estimated to be 15 deaths per 100 000 pregnancies. The majority of these deaths were associated with the use of the Dalkon Shield, a device that has since been withdrawn from the market.

The treatment now recommended for a pregnancy with an IUD in situ may be summarized as follows:

(1) If the woman requests an induced abortion and this is legally available, the uterus should be evacuated and the IUD removed.

(2) If the woman wishes to continue with the pregnancy and the threads are visible, the device should be removed by gently pulling the threads.

(3) If the woman wishes to continue the pregnancy and the threads are not visible, there should be careful examination for possible complications. If there are any signs of intrauterine infection and sepsis, evacuation of the uterus under broad-spectrum antibiotic cover is mandatory.

6.2.2 Ectopic pregnancy

The IUDs, whether medicated or non-medicated, are effective against uterine pregnancy, but there is little or no protection against ectopic pregnancy (tubal or ovarian). Reviews of the statistical association between ectopic pregnancy and IUDs suggest that the risk of ectopic pregnancy among IUD users may be greater than among women using no contraception. Such data, however, are difficult to interpret because other factors may also vary between users and non-users of IUDs. Even if it is accepted that using an IUD involves a higher risk of ectopic pregnancy, the relative risk is still small, 1-1.2 per 1000 woman-years of use. There seems to be no difference in this risk between the non-medicated and any of the copper IUDs. It is possible that subclinical pelvic infection is the major factor responsible for the association of IUDs with ectopic pregnancy. The possibility of an ectopic pregnancy must be considered when any IUD user becomes pregnant or has amenorrhoea and/or irregular vaginal bleeding with cramping lower abdominal pain. A pregnancy test is positive in only 40% of ectopic pregnancies. Therefore, if an intrauterine pregnancy is not evident the patient should be referred preferably to a specialist or a hospital for observation or investigation. When evacuation of the uterus is carried out because of a suspected *early* pregnancy, either with the IUD *in situ* or where there is a recent history of IUD use, it is advisable to examine the curettings histologically for the presence of trophoblastic tissue to exclude the possibility of an ectopic pregnancy.

6.2.3 Pelvic inflammatory disease (PID)

One of the possible complications associated with use of an IUD is pelvic inflammatory disease. The risk is highest in the first few weeks following insertion and remains higher than in users of other contraceptive methods while the device is left *in situ*.

The accurate diagnosis of PID is difficult. The following, if present, suggest that there is PID:

- infection of the cervix,
- a temperature (oral) of 38°C or above,

- suprapubic tenderness and guarding,
- tenderness/pain on moving the cervix during pelvic examination,
- adnexal tenderness and/or adnexal palpable masses on one or both sides.

However, less severe forms of infection may certainly occur without any of these symptoms. A measurement of the erythrocyte sedimentation rate can be useful, though non-specific, in helping to confirm the diagnosis.

If mild pelvic inflammatory diseases is suspected, there is no agreement as to whether the IUD should be removed or not. According to the general principles of medicine, removal of the foreign body is an important step in combating an infection, but many mild infections can, in fact, be treated without removing the IUD. The resulting continued protection is important, since the removal of an IUD because of a suspended infection is often followed by an unwanted pregnancy. In the nulliparous woman, an inadequately treated PID may subsequently lead to blockage of the fallopian tubes and the inability to have children. In such cases the removal of the IUD and treatment with a broad-spectrum antibiotic is recommended, but an alternative fertility regulating method should also be provided.

Occasionally the infection can be much more severe, causing unilateral or bilateral pyosalpinx or tubo-ovarian abscesses. Such an infection requires the immediate removal of the device, hospital admission, and intensive antibiotic therapy. Surgical drainage of the tubo-ovarian abscess may be necessary.

6.2.4 Performation/translocation

Perforation of the uterus by an IUD usually occurs at one of three sites: in the uterine fundus, at the angle between the cervix and the body of the uterus or through the cervical wall itself. Perforation at one of the first two sites usually occurs at the time of the insertion; perforation at the third site can occur at any time, since the device can slowly work itself through the uterine or cervical wall (translocation).

Perforation occurs more frequently when insertions are performed between 48 hours and 6 weeks postpartum, because of the retraction and involution of the uterus and hence possible change in position of the IUD in the uterine cavity (the incidence of perforation is lower in the post-placental and early postpartum period). Perforation is more often associated with rigid devices with free and sharp ends, and those not conforming to the shape of the uterine cavity. Inserter systems without plungers that are based on "pull" techniques seem to be associated with perforation rates.

Perforation should be suspected if sharp pain occurs at insertion or if the threads are not visible at a follow-up examination. The accurate diagnosis of perforation into the abdomen requires referral to well equipped clinics or hospitals and the treatment usually involves the removal of the IUD by abdominal surgery.

If perforation occurs, the closed types of IUD or those containing copper should be removed as soon as possible. Closed devices such as the ring or bow, can cause bowel strangulation while copper devices produce an intense tissue reaction (inflammation) leading to the formation of peritoneal adhesions.

6.3 Specific clinical problems

6.3.1 The IUD in nulliparous women

Clinical experience shows that nulliparous women, particularly young girls soon after menarche, have more problems with IUDs, such as expulsions and lower abdominal pain, than other women. There is also evidence (so far limited to developed countries) that these women have a higher risk of developing pelvic infections while using the IUD.

With medicated IUDs, which are smaller and more pliable, it has become easier to provide intrauterine contraception for nulliparous women following careful screening and counselling. It is preferable to suggest the use of IUDs to nulliparous women only if they cannot use or accept alternative methods or contraception. Of the IUDs discussed in Annex 1, the Copper-7 or TCu and the Nova T are usually preferred.

6.3.2 The IUD in women approaching the menopause

During this period of life the risk of cancer increases. Therefore, the bleeding irregularities that are often connected with IUD use may worry the woman and the health worker concerned. However, the use of the IUD in women approaching the menopause has the advantage that it does not interfere with natural cyclic bleeding and therefore the woman knows when she has reached her menopause. At this time a woman's overall fertility is decreased and her choice of fertility regulating method should be made taking this into account, as well as the increased risk of complications. Oral contraceptives, long-acting injectable contraceptives, if available, or sterilization, are other alternatives during this period. However, long-acting injectable hormonal contraceptives are associated with menstrual disturbances, and the risk of cardiovascular disease in association with oral hormonal contraceptives increases with age.

6.3.3 Postpartum insertion of IUDs

Insertion of an IUD after delivery can be performed:

(a) immediately after the expulsion of the placenta - "postplacental insertion",

(b) during the first week after delivery - "immediate postpartum insertion",

(c) from 1-6 weeks after delivery - "puerperal or delayed insertion", or

(d) at a follow-up examination 6-8 weeks after delivery - "postpuerperal insertion".

"Postplacental insertion" has several advantages for family planning programmes, particularly in those areas where contact with women using family planning is infrequent and where the supervised puerperal care is short. The motivation for contraceptive use is usually high at the end of a pregnancy and the insertion of an IUD provides immediate fertility regulation without interfering with lactation, as may happen with some of the hormonal contraceptives. A recent WHO study of three different devices (TCu, Lippes Loop D, Copper-7)

allayed the earlier fears concerning the possibilities of infection and prolonged bleeding following postplacental IUD insertion. The study did, however, confirm that insertion of an IUD immediately after expulsion of the placenta, results in an unacceptably high rate of expulsion and subsequent pregnancy. This applies to all of the IUDs currently available.

The advantage of the "immediate postpartum insertion" is the same as for the postplacental insertion discussed above. This method was first used in several developing countries during the national family planning programmes in the 1960s. There was found to be a high frequency of expulsion perforation/translocation, and infection. Because of the expulsion rates, which are typical for insertions carried out at this time, it is essential that there is a follow-up examination of the woman and that the device is reinserted, if necessary.

Similar results have been obtained using "puerperal or delayed insertion". Insertion at this time is not recommended since during this period of the puerperium there is an increased risk of perforation of the soft uterine wall and of infection.

"Postpuerperal insertion" of an IUD has several advantages. It can be combined with the follow-up examination of the woman and her child by the doctor or midwife. The results of these insertions are comparable with the interval insertions in menstruating women.

6.3.4 Post-abortion insertion of IUDs

The insertion of an IUD immediately after a woman has come to the clinic for an abortion has obvious service advantages; it is also a time when a woman is usually highly motivated for birth control. There has been some reluctance, however, to insert an IUD at this time since it may result in pelvic sepsis or a higher rate of uterine perforation than insertion at the more conventional time.

Recently completed WHO multicentre studies using the Copper TCu-220 C, Lippes Loop D, and Copper-7 have shown that there is no greater risk of pelvic inflammatory disease when an IUD is inserted immediately after a

legally induced abortion than following the normal interval insertion. The removal rates because of PID after two years were low. The expulsion and pregnancy rates were similar to those found following interval insertion.

The most striking results in this WHO study were the significantly higher expulsion rates following second trimester abortion. Three months after insertion, these ranged from a ten-fold difference for the Lippes Loop and the TCu-220 C to a five-fold increase for the Copper-7.

In conclusion IUD insertion following first trimester abortion is as safe and effective as interval insertion, but IUD insertion following second trimester abortion is not recommended with the IUDs and insertion techniques used at present.

When the abortion has been spontaneously or illegally induced, the risk of infection from immediate IUD insertion is considered to be potentially high, and, in the absence of specific data, there has been some reluctance to insert an IUD at this time. A WHO study has shown that the risk of infection after IUD insertion following a first trimester spontaneous abortion in women without clinical signs of infection seems to be comparable with that following insertions after legally induced abortions at the same stage of pregnancy.

Some randomized trials have shown that even when the abortion is accompanied by signs of an infection, there is no significant increase in the duration of fever or of hospitalization among IUD users. However, most physicians still do not approve of IUD insertion when there is an infection because of the risk that the infection will spread during the post-insertion period.

7. LONG-TERM SAFETY OF THE IUD METHOD

7.1 Mortality associated with IUD use

Mortality associated with IUD use is very low and has been estimated to be one death per 100 000 woman-years of use, the deaths usually following complications such as sepsis or ectopic pregnancy. When compared with other contraceptive methods, the IUD is safer than oral contraceptives, particularly in older or high-risk patients. Table 2 shows the relative mortality risk for IUD and oral contraceptive users compared with birth- and abortion-related mortality.

TABLE 2. COMPARATIVE MORTALITY RISKS (DEVELOPED COUNTRIES) PER 100 000 WOMEN, RELATED TO CONTRACEPTIVE USE AND TO CHILDBIRTH[a]

	Age	
	20-24 years	35-39 years
Birth-related (without contraception)	5.8	20.8
Abortion-related (without contraception)	1.9	2.9
Oral contraception: non-smokers	1.3	9.7
smokers	4.4	31.9
IUD	1.0	2.0

[a] from C. Tietze: Induced abortion 1979. A Population Council factbook, New York, The Population Council, 1979.

7.2 Cancer

Follow-up examinations of IUD users (both medicated and non-medicated devices) with routine Papanicolaou smears and periodic endometrial curettage have not shown any evidence that IUDs cause or promote cervical or endometrial cancer.

7.3 Teratogenesis

Although there is an increased risk of spontaneous abortion in pregnancies with IUDs *in situ*, there is no evidence to show that these abortions result from developmental abnormality of the foetus or embryo. Nor is there any evidence of increased congenital malformations among the offspring of either former users of IUDs or those who conceive with an IUD *in situ*.

7.4 Effect on subsequent fertility

The data available suggest that fertility is not significantly impaired in users of any type of IUD, particularly those who have used them for less than three years. There are no meaningful data available on the effects of the long-term use of the IUD on subsequent fertility. Most long-term IUD users are women who have completed their family rather than women who are spacing births, and therefore they tend to belong to the older age-groups with naturally declining fertility. The effect of IUD use on subsequent fertility needs further investigation, especially in view of recent evidence showing increased incidence of pelvic inflammatory disease in young nulliparous women, using IUDs.

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Annex 1

DIFFERENT TYPES OF DEVICE

Non-medicated or inert devices are usually made from polyethylene, polypropylene, other polymers, or stainless steel. Bioactive or medicated devices release either metal ions (copper) or hormones (progesterone, levonorgestrel). Barium sulfate is incorporated into the plastic devices to make them radio-opaque.

Non-medicated devices are often produced in several sizes to fit different sized uterine cavities. The Lippes Loop, for example, exists in four sizes, A, B, C, and D, the latter being the largest. A larger sized device usually has a greater antifertility effect and a lower explusion rate than a smaller version of the same device, but the removal rate because of pain and bleeding is higher. The medicated devices were developed to overcome this problem by using smaller sized devices (e.g., Copper-7 and TCu) with increased antifertility effects due to the incorporation of a system for the constant release of metal ions or steroid hormones.

If the area of contact between the device and the endometrial surface is increased, the pregnancy rate decreases, but bleeding and/or pain usually increases. For the medicated copper IUDs, the antifertility effect is directly related to the surface area of the copper coating (usually this is 200 or 220 mm^2).

The position of the device in the uterus also influences its effectiveness; the higher up in the uterus the device is placed (fundal position), the greater its effectiveness. This is particularly important for postpartum and postabortal insertions. Trials are in progress to investigate the possibilities of retaining the device in the higher position after insertion and thus reducing expulsion rates by the addition of catgut knots to standard IUDs.

IUDs are sometimes subdivided according to shape into "open" and "closed" devices. A closed device is one in which the polyethylene material is in the form of a ring (e.g., Ota Ring). An open device is any one which is not "closed", for instance the TCu; also included are loops such as the Lippes Loop and spirals like Saf-T Coil. Some of the closed devices have recently been either redesigned or withdrawn from the market because of the possible risk of bowel strangulation and severe peritonitis if the IUD perforates the uterus and enters the abdominal cavity. This complication is rare, however, and some large family planning programmes continue to use closed devices without any apparent problems.

Devices may be designed either to fill the cavity or to be retained by a spring-like action of the limbs (Copper T, Copper-7). The current trend is to reduce the size and rigidity of the device so that it fits smoothly into the uterine cavity while increasing its efficiency by the incorporation of bioactive substances. The "T" shape continues to be widely used in the newer medicated devices because of the ease of insertion and removal, the low expulsion rate, and the lower incidence of side-effects. Research is in progress to increase the life span of medicated devices so as to reduce the necessity for frequent changes.

Most devices used at present have one or more threads that project through the cervix into the vagina. No increased risk of pelvic infection is believed to be associated with these threads. However, it has been shown that the multiple-filament tail (as used in the Dalkon Shield, now withdrawn from the market) can harbour pathogenic bacteria and because of its wick-like action, it is associated with an increased risk of septic abortion if pregnancy occurs. There is a real, though small, increased risk of pelvic inflammatory disease among IUD users and there has been further investigation into whether the threads may be one of the causes. However, the results do not yet show any difference in the incidence of pelvic inflammatory disease between devices with or without monofilament cervical threads.

Commonly used devices[a]

Only five devices, the Lippes Loop, Copper-7, TCu-200, TCu-220C, and Multiload Copper 250 will be discussed in detail here; these are the ones most commonly used and for which scientific data are available. The Lippes Loop, TCu-200, TCu-220C, and Copper-7 are the established standard devices against which others are measured. The Population Information Program (Johns Hopkins University, Baltimore, Maryland, USA) in its Population Reports Series (see Bibliography) describes a wider variety of IUDs.

(a) Lippes Loop

This serpentine plastic device (Fig. 1) has been widely used for over 15 years and the protection it affords and its side-effects are well established. Only the larger size C and D loops are in common use and they are more suitable for multiparous women. The device is inserted into the uterus using a push technique; the flange on the inserter is fixed so as to bring the top of the device to the fundus in a normal uterine cavity of 7 cm. The device has now been given a slightly bulbous tip to reduce the risk of perforation.

This device is distributed by the Ortho Pharmaceutical Corporation, Raritan, New Jersey 08869, USA, and by Finishing Enterprises Inc., 908 Niagara Falls Blvd., North Tonawanda, New York 14120, USA. The Population Council, New York, grants licences for manufacture of the Lippes Loop and has supplied moulds and materials to national family planning programmes in India and some other developing countries.

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[a] The illustrations on pages 44 - 48 are reproduced from Population Reports, Series B, No. 3, 1979, with the permission of the Population Information Program.

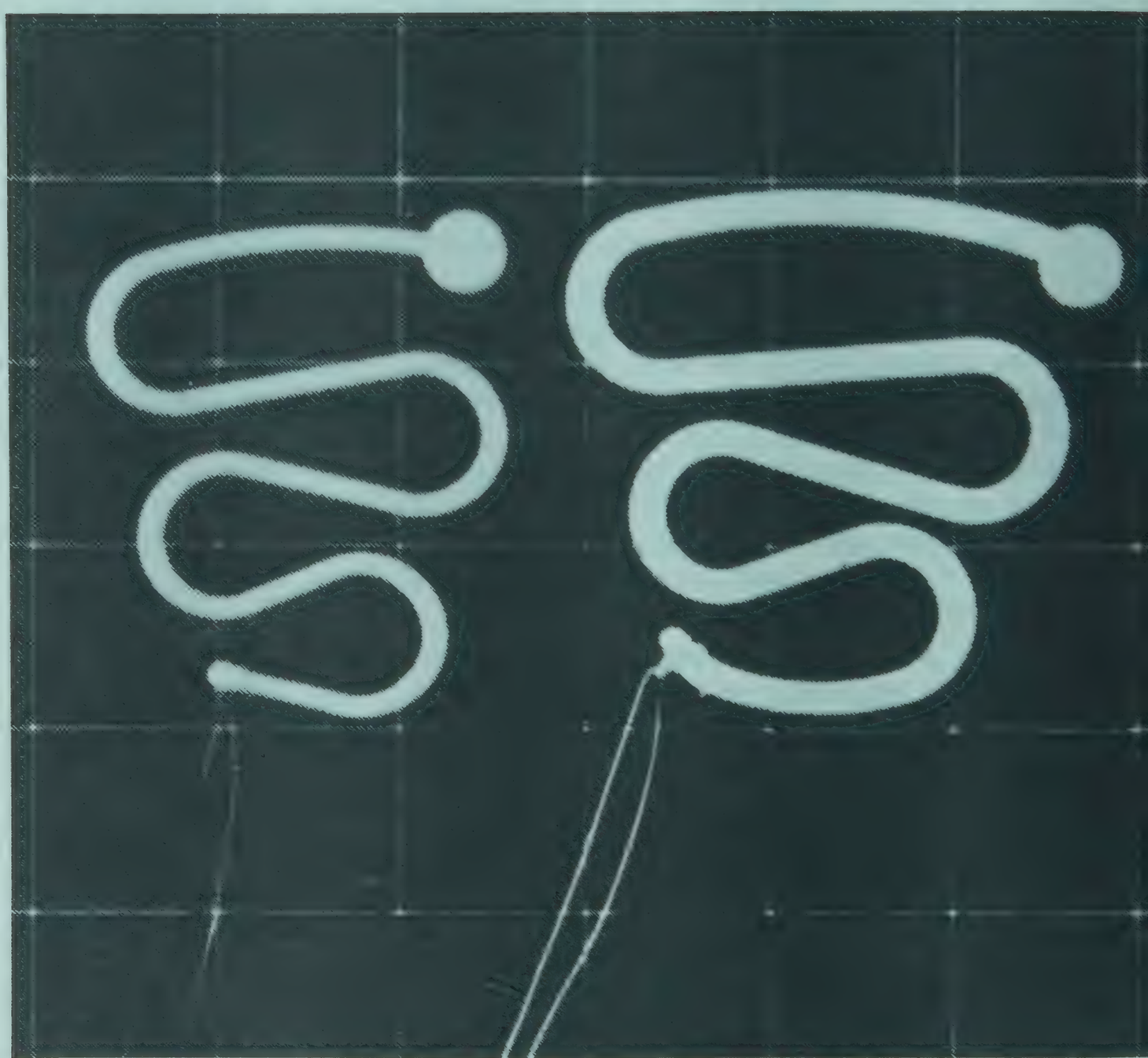

Fig. 1. Lippes Loop.

(b) TCu-200 or Gyne T

This device (Fig. 2) has a copper wire of 200 mm^2 surface area around the stem, and two transcervical nylon threads. It has a minimum effective life span of three years.

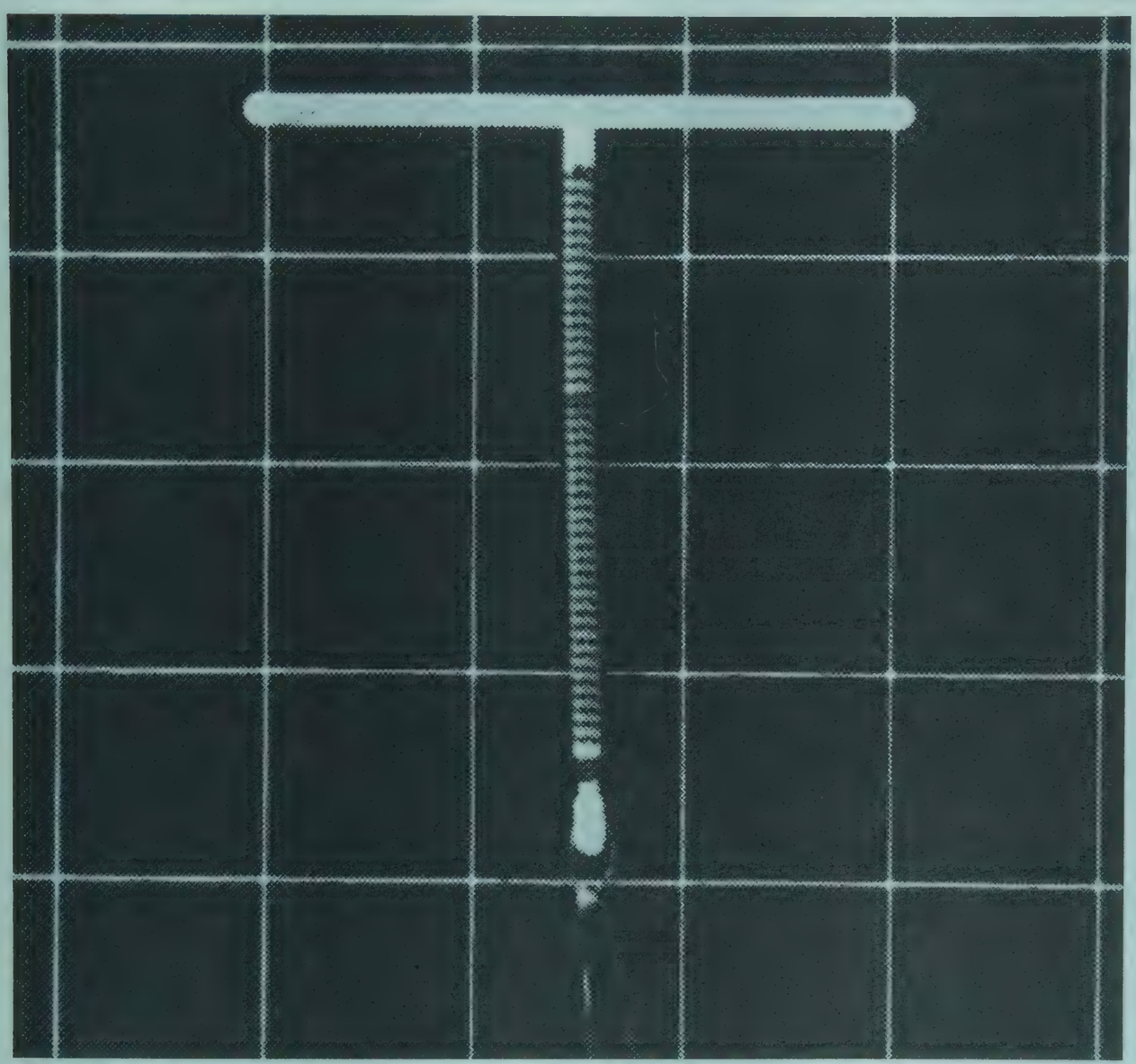

Fig. 2. TCu-200 or Gyne T.

Distributors are: AB Kabi, Stockholm, Sweden; G. D. Searle & Co., Chicago, Illinois 60680, USA; Outokumpu Oy, Pori, Finland; Ortho Pharmaceutical Ltd., High Wycombe, England; Schering AG, Berlin (West); Leiras, Turku, Finland.

(c) TCu-220 C

A modified version of the TCu-200, the TCu-220 C is being developed by the Population Council (Fig. 3). This device has seven solid copper sleeves, two on the transverse arm and five on the stem, giving a total exposed copper surface of 220 mm^2 and an estimated effective life span of more than five years. Under sterile conditions, both limbs of the horizontal arm are fitted into the introducer. After the flange has been adjusted to the correct depth and inserted, the device is released by pulling.

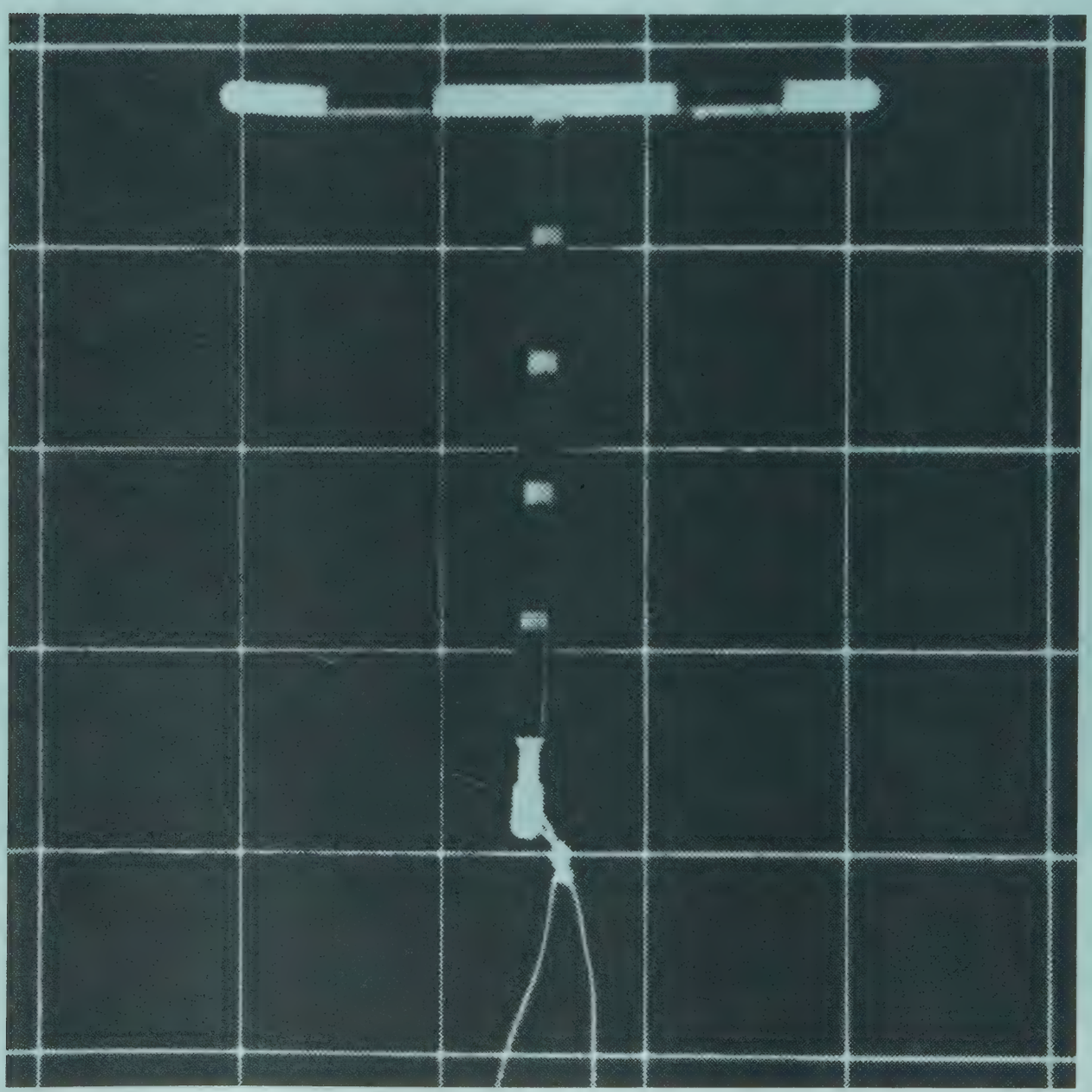

Fig. 3. TCu-220 C.

(d) Cu-7 or Gravigard

This device (Fig. 4) has copper wire with a surface area of 200 mm^2 wound around the shaft. There are bulbous expansions at the lower end and at the angle to prevent perforation, and a single transcervical thread. Under sterile conditions, the stem and the horizontal arm are pushed into the hollow inserter just before use, and the arm is released by pulling. Copper-7 has the introducer with the smallest diameter of all the IUDs currently available and it is easy to insert even in nulliparous women. It remains biologically active for at least two years, when it should be replaced, although it may be effective for longer periods. Research in progress indicates that copper devices may be effective for periods of up to four years.

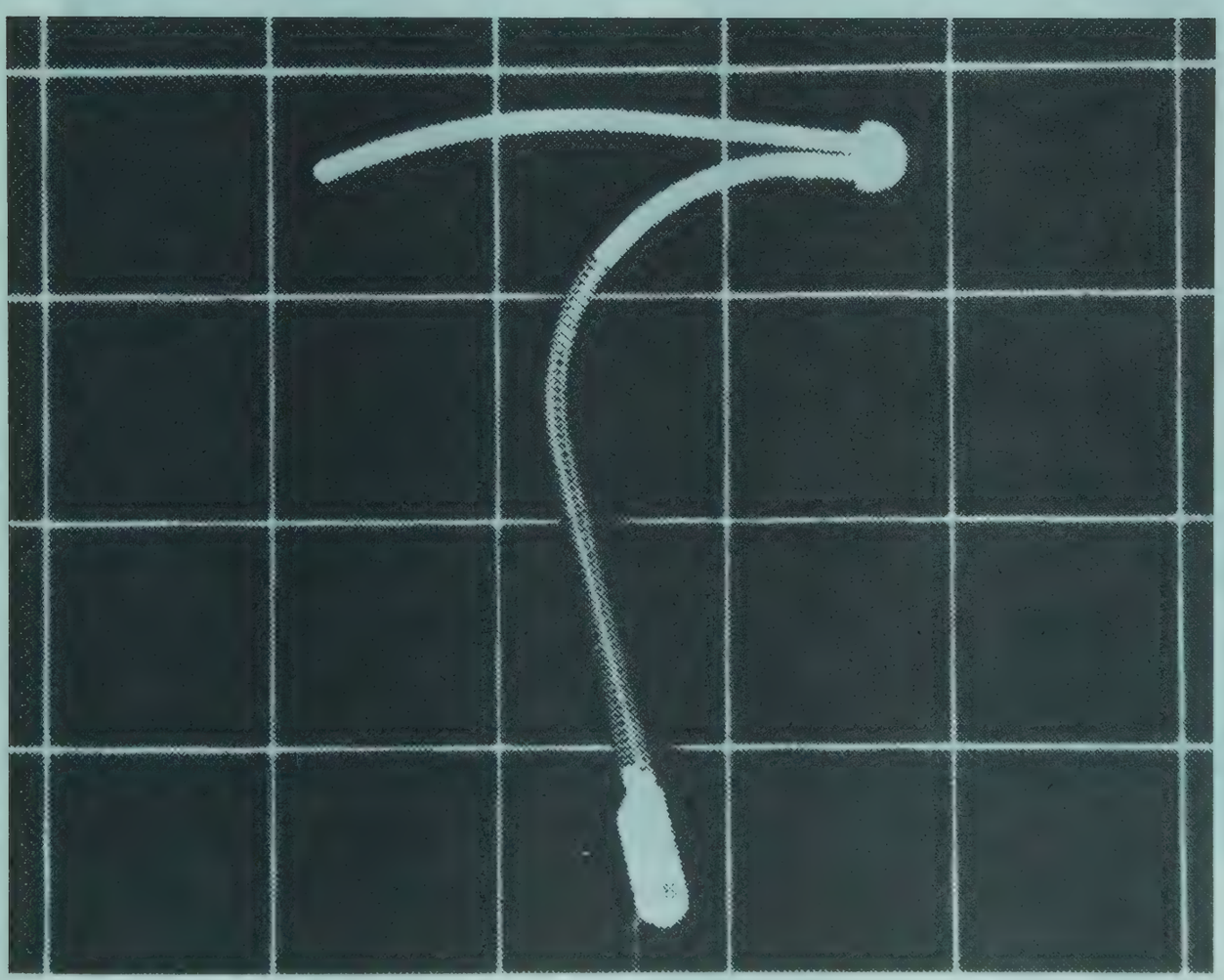

Fig. 4. Cu-7, or Gravigard.

This device is distributed by G. D. Searle & Co., Chicago, Illinois 60680, USA.

(e) Multiload-Cu250 or Multiload-D250

This device (Fig. 5) also carries a copper wire wound around the stem. The surface area of exposed copper is 250 mm^2. It is relatively easy to insert because of its pliable arms. The reported low expulsion rate, because of the serrated fins that hold the device in place in the cavity, has yet to be confirmed in randomized trials. According to the producers, the life span of the device is three years. A smaller version is available for use in nulliparous women and a new version, the Multiload Copper 375 with an estimated effective life span of five years is being developed.

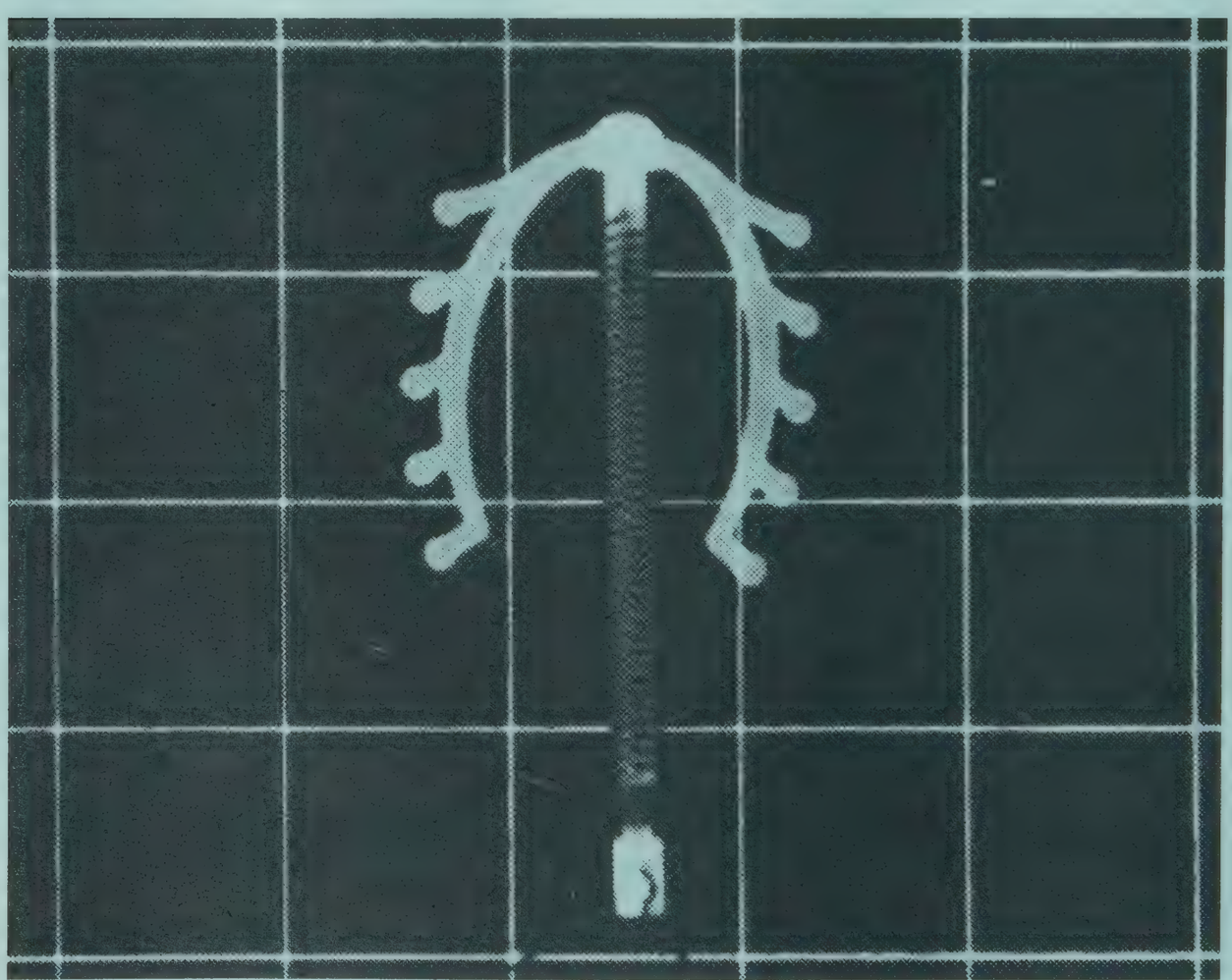

Fig. 5. Multiload-Cu250, or Multiload-D250.

This device is distributed by Multilan S.A., Fribourg, Switzerland, and in the future will be available from G. D. Searle Ltd, Canada, and Desberger Ltd, Montreal, Canada.

Insertion systems

Insertion systems vary as much as the devices in size, shape, and complexity. In the simplest system the IUD is attached to the distal end of the inserter and released by withdrawal (e.g., the Multiload). The device may be contained completely (e.g., the Lippes Loop) or partially (e.g., Copper-7 and T) in a hollow introducer to reduce its transverse diameter during its passage through the cervical canal. The device must be loaded immediately prior to insertion otherwise it may not resume its original shape after release from the inserter.

Since the method of loading and insertion varies from one device to another, the instructions provided by the manufacturer must be followed carefully. The ideal introducer should be easy to load, pass through the cervix easily, and place the device high in the uterine fundus, to reduce the risk of perforation.

Annex 2

EQUIPMENT AND REAGENTS FOR SIMPLE LABORATORY TESTS

1. Haemoglobin estimation

(a) Using a comparator

- haemoglobin comparator, with standards to cover the range 30-130 g of haemoglobin per litre
- two comparator tubes
- 50-µl (50-mm^3) pipettes
- haemoglobin diluting fluid - prepared by adding 0.04 ml of strong ammonia solution to one litre of distilled water.

(b) Sahli method (less accurate, but may be used if a comparator is not available)

- Sahli haemoglobinometer
- Sahli pipette (graduated to 20 µl, i.e., 20 mm^3)
- skin stylette
- small glass rod
- dropping pipette
- absorbent paper
- 1 litre of 0.1 mol/litre hydrochloric acid (HCL) - has to be renewed monthly.

2. Erythrocyte sedimentation rate (ESR)

- Westergren tube - internal diameter 2.5 mm, graduated from 0 to 200 mm
- Westergren stand
- 100 ml of anticoagulant - 38 g of trisodium citrate ($2H_2O$) per litre of water (must be kept in refrigerator)
- 5-ml graduated syringe
- timer.

3. Microscopy of vaginal discharge

- microscope (x40)
- glass slides
- inoculating loop
- modified Hucker crystal violet
- Gram's iodine solution
- 95% ethanol
- safranin solution
- tap water
- Bunsen burner or candle.

4. Collection of Papanicolaou smears

- glass slides
- wooden spatula
- transport container
- fixative (96% ethanol, ethanol and ether in equal parts, or ready-made spray fixative).

5. Pregnancy test

The majority of pregnancy tests are supplied by the manufacturer in kits which usually have to be stored in a refrigerator. Some of the tests are reliable from the time of the missed period, e.g., Neopregnosticon (Organon), while others are reliable only two weeks after a missed period. Recently home pregnancy testing kits have been developed, e.g., Predictor (Chefaro-Organon), which are simple to use, effective eight days after a missed period and do not produce false negative results due to prozone. However the cost involved in the use of pregnancy tests must be taken into consideration.

Annex 3

CHECKLISTS OF QUESTIONS AND INSTRUCTIONS[a]

Checklist for new IUD acceptors

QUESTIONS/OBSERVATIONS	Responses		INSTRUCTIONS
Ask the woman the following questions, and on pelvic examination be careful to look for the abnormalities listed	NO	YES	If the responses fall in a shaded box, be sure to follow the instructions below:
HISTORY			
1. Did your last full-term pregnancy end less than 4 weeks ago?	☐	■	1. If the delivery was normal and occurred more than 12 hours ago, you can insert an IUD. Exercise care to avoid perforation.
2. Have you had an abortion or miscarriage within the past 4 weeks?	☐	■	2. Women who have recently had a miscarriage or abortion can have an IUD inserted if there is: (*a*) no heavy bleeding, and (*b*) no sign of infection on pelvic examination. If you are unsure, refer the woman to a doctor.
3. Did your last period start more than 10 days ago?	☐	■	3. Insertion should be delayed until the next menstrual period and the woman advised to use other contraception in the meantime.
4. Do you consider that the bleeding during your menstrual periods is unusually heavy or do you often experience period pains severe enough to limit your daily life?	☐	■	4. Women with heavy menstrual bleeding or pain which limits normal activity are likely to have problems with an IUD. You should warn the woman and advise her to use another method.
5. Over the past 3 months have you had any abnormally heavy periods, bleeding between periods or after intercourse?	☐	■	5. These symptoms may indicate cancer and care should be exercised during pelvic examination.
6. Was your last period late or have you missed a recent period?	☐	■	6. Be careful to exclude the possibility of pregnancy during pelvic examination.
7. Over the past 3 months have you had fever or chills and pains in the lower abdomen?	☐	■	7. These symptoms may indicate pelvic inflammatory disease. Pay special attention to this possibility during pelvic examination.
8. On general examination, is there any marked pallor of the mucous membranes or conjunctiva suggestive of anaemia?	☐	■	8. Do not insert an IUD; refer to a doctor; give iron supplements.
BIMANUAL PELVIC EXAMINATION			
9. Is there marked tenderness of the cervix, uterus or adnexa?	☐	■	9. This suggests cervicitis or pelvic inflammatory disease. Do not insert an IUD. Refer to a doctor or treat according to your manual.
10. Is the cervix immobile, or is there a palpable mass or ulcer?	☐	■	10. These abnormalities may indicate carcinoma; refer to a doctor. Do not sound the uterus or insert an IUD.
11. Are you unable to determine the position of the uterus?	☐	■	11. If you are unsure of the position of the uterus after a bimanual palpation, do not insert the IUD. Refer the woman to a doctor.
12. Is the uterus enlarged, soft and smooth?	☐	■	12. If the woman has missed a period she is likely to be pregnant. Do not insert an IUD. Provide antenatal care. If unsure, refer to a doctor.
13. Is the uterus enlarged, firm and irregular?	☐	■	13. This indicates fibroids; refer to a doctor. Do not insert an IUD.
14. Is there a palpable mass in the adnexa?	☐	■	14. This may indicate pelvic inflammatory disease or a tumour of the ovary or tubes. Refer to a doctor.
SPECULUM EXAMINATION			
15. Is the vaginal wall inflamed, and or is there a discharge in the vagina?	☐	■	15. This suggests vaginitis. Exclude the possibility of pelvic inflammatory disease. See the manual for treatment of vaginitis before inserting an IUD.
16. Is the cervix red and inflamed, and is there discharge from the cervical canal?	☐	■	16. This suggests cervicitis or pelvic inflammatory disease. Do not insert an IUD. Refer to a doctor or treat according to the instructions in your manual.
17. Cervix: Is there a mass, ulcer or bleeding on contact?	☐	■	17. This suggests carcinoma; refer to a doctor.

[a] Reproduced from : GRAY, R.H. Manual for the provision of intrauterine devices (IUDs). Geneva, World Health Organization, 1980.

Checklist for follow-up of IUD users

QUESTIONS/OBSERVATIONS	Response		INSTRUCTIONS
Ask the woman the following questions, and on pelvic examination be careful to look for the abnormalities listed	NO	YES	If the responses fall in a shaded box, be sure to follow the instructions below:
HISTORY			
Since I last saw you:			
1. Have you had intermenstrual bleeding or heavy or prolonged bleeding?	☐	▩	1. If during the first 3 months after insertion, reassure the woman that this is likely to decrease with time. Provide iron supplements. On pelvic examination be sure to exclude other pathology, especially if these problems occur more than 3 months after insertion. Remove the IUD if the woman finds these symptoms intolerable. Refer if ncecessary.
2. Have you had pain severe enough to limit your normal life?	☐	▩	2. If this occurs during the first 3 months after insertion, reassure and provide analgesics. If the woman finds this intolerable remove the IUD.
3. Was your last period late or have you missed a recent period?	☐	▩	3. Be careful to exclude the possibility of pregnancy during pelvic examination.
4. Have you had fever or chills, and pains in the lower abdomen?	☐	▩	4. These symptoms may indicate pelvic inflammatory disease. Give special attention to this possibility during pelvic examination.
5. Has the IUD been expelled?	☐	▩	5. Reinsert, if the woman agrees and there are no contraindications.
BIMANUAL PELVIC EXAMINATION			
6. Is there marked tenderness of the cervix, uterus or adnexa?	☐	▩	6. This suggests pelvic inflammatory disease or cervicitis. Refer to a doctor or treat according to the instructions in your manual.
7. Is the uterus enlarged, soft and smooth?	☐	▩	7. If the woman has missed a period, she is likely to be pregnant. Refer to a doctor.
8. Is there a mass in the adnexa?	☐	▩	8. Refer to a doctor.
SPECULUM EXAMINATION			
9. Is the IUD thread visible?	☐	▩	9. If the IUD threads are not visible, ask the woman to return during her next menstrual period, and advise her to use additional contraceptive protection. If the threads are not visible during menstruation, refer her to a doctor.
10. Is the stem of the IUD protruding through the cervix?	☐	▩	10. This is a partial expulsion. Remove the IUD. If there no contraindications and the woman agrees, reinsert an IUD.
11. Is the vaginal wall inflamed and/or is there a discharge in the vagina?	☐	▩	11. This suggests vaginitis. See manual for treatment.
12. Is the cervix red and inflamed, and is there discharge from the cervical canal?	☐	▩	12. This suggests cervicitis or pelvic inflammatory disease. Refer to a doctor or treat according to the instructions in your manual.
13. Is there profuse bleeding from the cervical os?	☐	▩	13. If this is intermenstrual bleeding more than 3 months after insertion, or if there is any indication of pregnancy, refer to a doctor.
14. Cervix: Is there a mass, ulcer or bleeding on contact?	☐	▩	14. This suggests carcinoma; refer to a doctor.

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